

12-14-05

DAC
JW

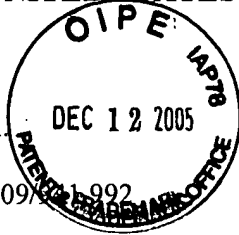
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kevin P. BAKER, et al.

Application Serial No. 09/021,992

Filed: August 28, 2001

For: **SECRETED AND TRANSMEMBRANE
POLYPEPTIDES AND NUCLEIC
ACIDS ENCODING THE SAME**

Examiner: Kemmerer, Elizabeth

Art Unit: 1646

Confirmation No. 8312

Attorney's Docket No. 39780-2730 P1C1

Customer No. 35489

EXPRESS MAIL LABEL NO. EV 765 988 830 US
DATE MAILED: DECEMBER 12, 2005PETITION FOR DESIGNATION AS NEW GROUNDS OF REJECTION
UNDER 37 C.F.R. §1.181

MAIL STOP PETITION

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

This Application is under Appeal. An Examiner's Answer was mailed on October 12, 2005 in this case. This petition is filed:

☒ within two months of the mailing of the Examiner's Answer.

The proposed Reply Brief

- ☐ has been filed;
☒ is attached;
☒ with a request for Oral Hearing; and
☒ a Petition for designation of new grounds of rejection in the Examiner's Answer under 37 CFR §1.181

12/15/2005 SDENB0B1 00000042 081641 09941992

The application status is:

01 FC:1464 130.00 DA

- ☐ Small Entity—fee \$
☒ Large Entity—fee \$
☐ Enclosed is Check No. _____ in the amount of \$ _____.
☒ The Commissioner is authorized to charge (or credit any overpayment) Deposit Account No. 08-1641 (referencing Attorney's Docket No. 39780-2730 P1C1) in the amount of \$130.00 for the Petition Fee.

12/15/2005 SDENB0B1 00000031 081641 09911992

01 FC:1464 130.00 DA

Void date: 12/15/2005 SDENB0B1
12/15/2005 SDENB0B1 00000031 081641 09911992

01 FC:1464

130.00 CR

STATEMENT

An Appellants' Appeal Brief was filed on July 26, 2005 and an Examiner's Answer was mailed on October 12, 2005 in this case. Concurrent with the filing of this Petition, Applicants are filing a Reply Brief and a request for an Oral Hearing.

Appellants submit that a number of grounds of rejection set forth in the Examiner's answer mailed on October 12, 2005 constitute new grounds of rejection. Appellants request that the grounds of rejection identified below and the six new references which are being cited in the Examiner's Answer in support of the grounds of rejection be designated new grounds of rejection. Appellants request a corrected Examiner's Answer which identifies the rejections as new grounds for rejection. Appellants further request that prosecution be reopened.

The Examiner has raised six new references for the first time in the Examiner's response. They are:

- (1) Hittelman, 2001, Ann NY Acad. Sci 952:1-12;
- (2) LaBaer; 2003, Nature Biotechnology 21:976-977;
- (3) Chen *et al.*; 2002, Molecular and Cellular Proteomics 1:304-313;
- (4) Gygi *et al.*; 1999, Mol. Cell. Biol. 19:1720-1730;
- (5) Lian *et al.* 2001, Blood 98:513-524; and
- (6) Fessler *et al.*, 2002, J. Biol. Chem. 277:31291-31302.

These references were not previously cited in any of the prior rejections of record. Appellants submit that the citation of such new prior art references for the first time in an Examiner's answer constitutes a new ground of rejection and is not permissible.

Legal Analysis

The M.P.E.P. Section 1207.03 (III) states that:

A new prior art reference cited for the first time in an examiner's answer generally will constitute a new ground of rejection. If the citation of a new prior art reference is necessary to support a rejection, it must be included in the statement of rejection, which would be considered to introduce a new ground of rejection. Even if the prior art reference is cited to support the rejection in a minor capacity, it should be positively included in the statement of rejection. *In re Hoch*, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n. 3 (CCPA 1970). However, where a newly cited reference is added merely as evidence of the prior well known statement made by the examiner, the citation of the reference in the examiner's answer would not constitute a new ground of rejection within the meaning of 37 CFR §1.192(a)(2). See also MPEP §2144.03.

The M.P.E.P. adds that:

In addition, if an Appellant has clearly set forth an argument in a previous reply during prosecution of the application and the Examiner has failed to address that argument, the Examiner would not be permitted to add a new ground of rejection in the Examiner's answer to respond to that argument but would be permitted to reopen prosecution, if appropriate. (Emphasis added; See M.P.E.P. §1207.03; Requirements for a new ground of rejection, II).

The Court of Customs and Patent Appeals considered this situation in *In re Hoch*, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n. 3 (CCPA 1970). In that case there were two other references cited in the appeal which were not mentioned in the statement of either of the appealed rejections. The court held:

Appellant's complaint seems to be justified, and if we did not find the rejections based solely on Molotsky and the French patent to be sound, we might well feel constrained to reverse the decision of the board. Where a reference is relied on to support a rejection, whether or not in a "minor capacity" there would appear to be no excuse for not positively including the reference in the statement of rejection.

Appellants note that a Reply Brief must be in compliance with the requirements set forth in 37 C.F.R. §41.41. New or non-admitted affidavits and/or other evidence are not permitted in a reply brief.

For the detailed reasons set forth below, Appellants submit that the citation for the first time of these six references constitute a new ground of rejection and accordingly such rejections are not permissible.

Detailed Analysis

(1) Hittelman, 2001, Ann NY Acad. Sci 952:1-12

The Examiner cites Hittelman for the first time on pages 5, line 17 - page 6, line 11, where the Examiner states:

"the literature reports that lung epithelium is at risk for cellular damage due to direct exposure to environmental pollutants and carcinogens, which result in aneuploidy *before* the epithelial cells turn cancerous. See Hittelman who teach that damaged, precancerous lung epithelium is often aneuploid. See especially p.4, Figure 4. The gene amplification assay in the specification does not provide a direct comparison between the lung tumor samples and normal lung epithelium."

The Examiner cites Hittelman throughout the Examiner's Answer at, for example, page 14, lines 15-17; page 17, lines 8-15; page 25, lines 7-12; and page 31, lines 2-19.

The Examiner had not previously raised the issue of aneuploidy in damaged precancerous lung epithelium or the citation, Hittelman.

Appellants submit that they are unable to adequately rebut the Hittelman reference and each of the rejections based on Hittelman without presenting substantive evidence of their own. The M.P.E.P.

and the case law clearly state that the Examiner is not allowed to make new grounds of rejection and cite a new reference. Furthermore, it is inequitable to allow the Examiner to do so without allowing Appellants to present evidence in rebuttal. Appellants submit that the citation of Hittelman and raising of the grounds of rejection based on Hittelman constitute new grounds of rejection.

(2) LaBaer; 2003, Nature Biotechnology 21:976-977

The Examiner cites LaBaer for the first time on page 7, line 22 - page 8, line 4; where she states that:

“One of the authors of this paper, Dr. LaBaer made an even stronger statement that reports of mRNA or protein changes of as little as two fold are not uncommon, and although changes of this magnitude may turn out to be important, most are attributable to disease-independent differences between the samples.”

The Examiner cites LaBaer throughout the Examiner's Answer, for example, in support of rejections at page 11, lines 6-7; page 12, lines 5-7; page 14, line 19 - page 15, line 2; page 18, line 18 - page 19, line 1; page 22, line 19 - page 23, line 1; page 25, lines 14 - page 26, line 7; page 27, lines 13-19, page 28, lines 14-18; page 29, lines 16-19; page 39, lines 18-21; page 44, lines 15-22; page 48, lines 11-19; and page 51, lines 11-19.

In this case, the Examiner's basis for rejection that differences of as little as two fold are not uncommon and that changes of this magnitude relate to disease-independent differences between the samples” is being made for the first time.

Appellants submit that they are unable to adequately rebut the LaBaer reference and each of the rejections based on LaBaer without presenting substantive evidence of their own. The M.P.E..P. and the case law clearly state that the Examiner is not allowed to make new grounds of rejection and cite a new reference, LaBaer. Furthermore, it is inequitable to allow the Examiner to do so without allowing Appellants to present evidence in rebuttal. Appellants submit that the citation of LaBaer and raising of the grounds of rejection based on LaBaer constitute new grounds of rejection.

(3) Chen *et al.*; 2002, Molecular and Cellular Proteomics 1:304-313

The Examiner states at page 7, lines 6-14 of the Examiner's response that “Chen *et al.*, (2002, Molecular and Cellular Proteomics 1:304-313) compared mRNA and protein expression for a cohort of genes in the same lung carcinomas. Only 17% of 165 protein spots or 21% of genes had significant correlation between protein and mRNA expression levels. Chen *et al.* clearly state that “the use of mRNA expression patterns by themselves, however, is insufficient for understanding the expression of protein products.”

The Examiner makes reference to specific experimental details and statistical percentages present in the Chen reference for the first time. This constitutes a new ground of rejection.

The Examiner cites Chen throughout the Examiner's Answer, for example, in support of rejections at page 11, lines 4-10; page 12, lines 5-7; page 14, line 19 - page 15, line 2; page 16, lines 1-4; page 18, lines 2-10; page 22, lines 15-22; page 25, lines 14-20; page 27, lines 13-19; page 28, lines 10-14; page 29, lines 17-19; page 39, lines 18-20; page 41, line 16 - page 42, line 6; page 44, lines 13-15, page 48, lines 11-14 and page 51, lines 11-14.

Appellants submit that they are unable to adequately rebut the Chen reference and each of the rejections based on Chen without presenting substantive evidence of their own. The M.P.E.P. and the case law clearly state that the Examiner is not allowed to make new grounds of rejection and cite a new reference, Chen. Furthermore, it is inequitable to allow the Examiner to do so without allowing Appellants to present evidence in rebuttal. Appellants submit that the citation of Chen and raising of the grounds of rejection based on Chen constitute new grounds of rejection.

- (4) Gygi *et al.*; 1999, Mol. Cell. Biol. 19:1720-1730;
- (5) Lian *et al.* 2001, Blood 98:513-524; and
- (6) Fessler *et al.*, 2002, J. Biol. Chem. 277:31291-31302

Similarly, regarding (4) Gygi, (5) Lian and (6) Fessler, the Examiner cites these references for the first time in the Examiner's Answer on pages 8 through 9. The Examiner states that "Gygi conducted a similar study with over 150 polypeptides," "Lian show a similar lack of correlation in mammalian (mouse cells)," and "Fessler found poor concordance between mRNA transcript and protein expression changes in human cells." These references are presented for the first time and hence, constitutes a new ground of rejection.

These references are further cited throughout the Examiner's Answer in support of various rejections at, for example, page 11, lines 4-10; page 12, lines 5-7; page 14, line 19 - page 15, line 2; page 16, lines 1-4; page 19, line 8 - page 20, line 1, including a quote from Gygi; page 22, line 20 - page 23, line 1; page 25, lines 14-20; page 27, lines 13-19; page 28, lines 14-18; page 29, lines 17-19; page 39, lines 18-20; page 44, lines 13-15, page 48, lines 11-14 and page 51, lines 11-14.

Appellants submit that they are unable to adequately rebut these references and each of the rejections based on these references without presenting substantive evidence of their own. The M.P.E.P. and the case law clearly state that the Examiner is not allowed to make new grounds of rejection and cite a new reference. Furthermore, it is inequitable to allow the Examiner to do so without allowing Appellants to present evidence in rebuttal. Appellants submit that the citation of these references and

raising of the grounds of rejection based on these references constitute new grounds of rejection.
Appellants further request that prosecution be reopened.

Appellants submit that this issue of the new grounds of rejections is being timely raised by the filing of this petition under 37 C.F.R. §1.181 with necessary fees and concurrently, with the filing of a Reply Brief within the two month period set for the Appellants' response.

Respectfully submitted,

Date: December 12, 2005

By: Leslie Mooi
Leslie A. Mooi (Reg. No. 37,047)

HELLER EHRMAN LLP
275 Middlefield Road
Menlo Park, California 94025
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

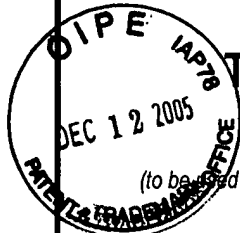
SV 2173381 v2
12/12/05 4:51 PM (39780.2730)

Please type a plus sign (+) inside this box ☐

PTO/SB/21 (6-99)

Approved for use through 09/30/2000. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	09/941,992
		Filing Date	AUGUST 28, 2001
		First Named Inventor	KEVIN P. BAKER
		Group/Art Unit	1646
		Examiner Name	KEMMERER, ELIZABETH
Total Number of Pages in This Submission	8	Attorney Docket Number	39780-2730 P1C1

ENCLOSURES (check all that apply)

☒ FEE TRANSMITTAL FORM

- ☐ Fee Attached
- ☐ Amendment
 - ☐ After Final
 - ☐ Version With Markings Showing Changes
 - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
 - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
 - ☐ Copy of Notice

- ☐ Copy of an Assignment
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- ☒ PETITION FOR DESIGNATION AS NEW GROUNDS OF REJECTION UNDER 37 C.F.R. §1.181
- ☐ Power of Attorney, by Assignee to Exclusion of Inventor Under 37 C.F.R. §3.71 With Revocation of Prior Powers
- ☐ Terminal Disclaimer
- ☐ Small Entity Statement
- ☐ Request for Refund

- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter

☒ ADDITIONAL ENCLOSURE(S) (PLEASE IDENTIFY BELOW):

☒ STAMPED RETURN POSTCARD

Remarks

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT 08-1641 FOR ANY FEES DUE IN CONNECTION WITH THIS PAPER, REFERENCING ATTORNEY'S DOCKET NO. 39780-2730 P1C1.

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm or Individual name	HELLER EHRMAN LLP		LESLIE A. MOOI (Reg. No. 37,047)	
	275 Middlefield Road, Menlo Park, California 94025	Telephone: (650) 324-7000	Facsimile: (650) 324-0638	
Signature	<i>Leslie Mooi</i>			
Date	DECEMBER 12, 2005	Customer Number:	35489	

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated below and addressed to: **MAIL STOP PETITION**, Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450, on this date: **DECEMBER 12, 2005**

Express Mail Label **EV 765 988 772 US**

Typed or printed name	C. FONG		
Signature	<i>C. Fong</i>	Date	DECEMBER 12, 2005

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop ____, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2005

Effective 10/03/2003. Patent fees are subject to annual revision.

☐ Claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 130.00

Complete if Known

Application Number 09/941,992
Filing Date AUGUST 28, 2001
First Named Inventor KEVIN P. BAKER
Examiner Name KEMMERER, ELIZABETH
Art Unit 1646
Attorney Docket No. 39780-2730 P1C1

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number 08-1641 (39780-2730 P1C1)
Deposit Account Name HELLER EHRMAN LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 300	2001 150	Utility filing fee	
1002 200	2002 100	Design filing fee	
1003 200	2003 100	Plant filing fee	
1004 300	2004 150	Reissue filing fee	
1005 200	2005 100	Provisional filing fee	
SUBTOTAL (1) (\$)			

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 50	2202 25	Claims in excess of 20
1201 200	2201 100	Independent claims in excess of 3
1203 360	2203 180	Multiple dependent claim, if not paid
1204 200	2204 100	** Reissue independent claims over original patent
1205 50	2205 25	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 120	2251 60	Extension for reply within first month	
1252 450	2252 225	Extension for reply within second month	
1253 1,020	2253 510	Extension for reply within third month	
1254 1,590	2254 795	Extension for reply within fourth month	
1255 2,160	2255 1,080	Extension for reply within fifth month	
1401 500	2401 250	Notice of Appeal	
1402 500	2402 250	Filing a brief in support of an appeal	
1403 1,000	2403 500	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 500	2452 250	Petition to revive - unavoidable	
1453 1,500	2453 750	Petition to revive - unintentional	
1501 1,400	2501 700	Utility issue fee (or reissue)	
1502 800	2502 400	Design issue fee	
1503 1,100	2503 550	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	130.00
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))	
1801 790	2801 395	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 130.00

SUBMITTED BY

(Complete if applicable)

Name (Print/Type) LESLIE A. MOOI Registration No. 37,047 Telephone (650) 324-7000
Signature Date DECEMBER 12, 2005

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.